PrecisionBioLogic

8672 '99 JUL 28 A9:24

July 27, 1999

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Reference: Docket No. 98N-1215 Foreign Establishment Registration and Listing

To Whom It May Concern:

Precision BioLogic is a small Canadian company that develops, manufactures and markets a line of diagnostic products used in clinical coagulation laboratories. We introduced our initial product offering to the US market in 1993, and now sell to a group of several hundred highly specialized laboratories in the US. Our products, all of which are FDA-registered, have gained an exceptional reputation for quality. We maintain a dedicated distribution facility in the US and most of the company's sales are now made to US customers.

We have reviewed the proposed rule on the above referenced docket and wish to voice our strong opposition to the concept of requiring foreign establishments to identify a United States agent. This would represent an unnecessary new level of inefficiency. We believe the proposal would be counter-productive for the following reasons:

1. We already have an official inhouse correspondent who handles communication directly with the FDA. We do not believe it would benefit either the FDA or ourselves to introduce an intermediary. We do not need a US agent to assist the FDA in communications with our company, to respond to questions regarding devices imported or offered for import, or to assist the FDA in scheduling inspections of our establishment. All of these things are accomplished much more efficiently by direct contact. Specifically, the introduction of an intermediary would:

   a. needlessly slow down communication between our company and the FDA dramatically, since everything would have to be done twice;

   b. needlessly increase the time required to register new products;

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c. needlessly increase the cost of getting new products to market, to the detriment of both our US customers and our company; and

d. needlessly increase the potential for confusion, since the matters we communicate with the FDA are quite complex and very technical in nature.

2. Our product line is highly specialized in nature and marketed to an extremely small sub-segment of the clinical laboratory community. The likelihood of finding an agent who understands our business, our products and our customers is very slim. The amount of time and resources we as a "small manufacturer" (as defined by the FDA) would have to invest to locate, train and interface with a US agent would in itself be burdensome, expensive, and time-consuming.

3. The proposal would encumber us with needless inefficiencies which US competitors do not face. The slowdown in process, coupled with the associated increase in costs, represents an unfair burden on non-US companies.

4. We believe the proposed legislation runs counter to NAFTA and GATT.

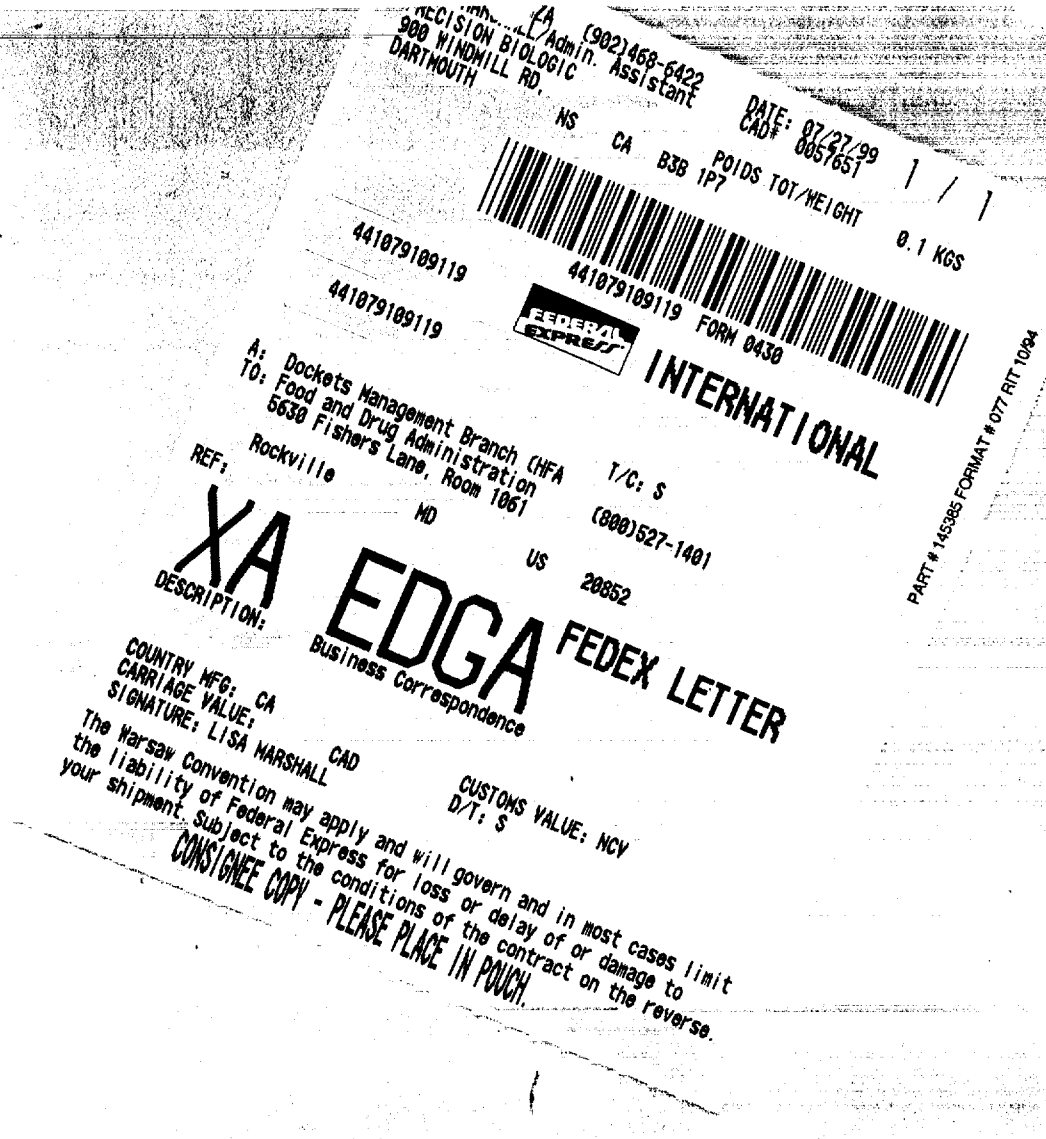
5. The increased costs and delays would require us to increase prices and/or prevent our established customers from gaining access to new products that they wish to purchase from us. Since our customers depend on our products for their superior effectiveness, this would impact their ability to provide quality results to health providers, thereby negatively affecting patient care for US citizens.

In sum, we feel that no party (neither the FDA, nor our customers nor our company) would benefit from this proposal.

Thank you for giving us this opportunity to voice our concerns and register our strong opposition to the proposed changes.

Yours truly,

Michael Scott
Chairman and CEO



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